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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/627,604	07/28/2003	Gregg A. Hastings	PF185D1C2	4279

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EXAMINER	
SAOUD, CHRISTINE J	
ART UNIT	**PAPER NUMBER**
1647	

DATE MAILED: 03/27/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/627,604	HASTINGS ET AL.	
	Examiner	Art Unit	
	Christine J. Saoud	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 January 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *17 and 21-36* is/are pending in the application.

4a) Of the above claim(s) *17* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *21-36* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *28 July 2003*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of Group II in the reply filed on 06 January 2006 is acknowledged. The traversal is on the ground(s) that a search of all the inventions together would not constitute a serious burden of search. Applicant asserts a search of the polypeptides would provide relevant information for the other claim groups such as the polynucleotides, antibodies, and methods of use and that the searches would overlap. This is not found persuasive because M.P.E.P. § 803 provides that the separate classification (i.e., class and subclass) of distinct inventions is sufficient to establish a *prima facie* case that the search and examination of the plural inventions would impose a serious burden upon the Examiner. MPEP (808.02) indicates that a serious burden of search can be established by separate classification of the inventions which shows that each invention has attained recognition in the art as a separate subject for inventive effort and also a separate field of search. Such separate classification was set forth in the previous Office action mailed and a *prima facie* case of serious burden of search has been established. Furthermore, Applicant has offered no evidence to rebut this showing.

The requirement is still deemed proper and is therefore made FINAL.

Claim 17 is withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking

claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 06 January 2006. Claims 21-36 are currently under examination.

Specification

Applicant is reminded of the proper content of an abstract of the disclosure.

A patent abstract is a concise statement of the technical disclosure of the patent and should include that which is new in the art to which the invention pertains. If the patent is of a basic nature, the entire technical disclosure may be new in the art, and the abstract should be directed to the entire disclosure. If the patent is in the nature of an improvement in an old apparatus, process, product, or composition, the abstract should include the technical disclosure of the improvement. In certain patents, particularly those for compounds and compositions, wherein the process for making and/or the use thereof are not obvious, the abstract should set forth a process for making and/or use thereof. If the new technical disclosure involves modifications or alternatives, the abstract should mention by way of example the preferred modification or alternative.

The abstract should not refer to purported merits or speculative applications of the invention and should not compare the invention with the prior art.

The abstract of the disclosure is objected to because it refers to speculative applications of the invention. Correction is required. See MPEP § 608.01(b).

Claim Objections

Claim 21 is objected to because of the following informalities: part (a) appears to be missing the word "to" between the terms "-23" and "183". For the purpose of examination, this claim will be interpreted as meaning "-23 to 183". Appropriate correction is required.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 21-36 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific and substantial credible asserted utility or a well established utility. The claimed invention is drawn to a protein with no apparent or disclosed specific and substantial credible utility. The instant application has provided a description of an isolated DNA encoding a protein and the protein encoded thereby. The instant application does not disclose the biological role of this protein or its significance.

It is clear from the instant specification that the growth factor-like protein described therein is what is termed an "orphan protein" in the art. This is a protein whose cDNA has been isolated because of its similarity to known proteins. There is little doubt that, after complete characterization, this protein may be found to have a specific and substantial credible utility. This further characterization, however, is part of the act of invention and until it has been undertaken, Applicant's claimed invention is incomplete. The instant situation is directly analogous to that which was addressed in *Brenner v. Manson*, 148 U.S.P.Q. 689 (Sus. Ct, 1966), in which a novel compound which was structurally analogous to other compounds which were known to possess anti-tumor activity was alleged to be potentially useful as an anti-tumor agent in the absence of evidence supporting this utility. The court expressed the opinion that all chemical compounds are "useful" to the chemical arts when this term is given its

broadest interpretation. However, the court held that this broad interpretation was not the intended definition of "useful" as it appears in 35 U.S.C. §101, which requires that an invention must have either an immediately obvious or fully disclosed "real world" utility. The court held that:

> "The basic quid pro quo contemplated by the Constitution and the Congress for granting a patent monopoly is the benefit derived by the public from an invention with substantial utility", "[u]nless and until a process is refined and developed to this point-where specific benefit exists in currently available form-there is insufficient justification for permitting an applicant to engross what may prove to be a broad field", and "a patent is not a hunting license", "[i]t is not a reward for the search, but compensation for its successful conclusion."

The instant claims are drawn to a protein of as yet undetermined function or biological significance. There is absolutely no evidence of record or any line of reasoning that would support a conclusion that a CCN-like growth factor of the instant application could be used in wound-healing and associated therapies, for tissue remodeling or for stimulating angiogenesis as stated at page 13 of the specification. Until some actual and specific significance can be attributed to the protein identified in the specification as CCN-like growth factor or SCGF, or the gene encoding it, the instant invention is incomplete. The DNA of the instant invention and the protein encoded thereby are compounds which are known to be structurally analogous to proteins which are known in the art as CCN growth factors. In the absence of a knowledge of the receptor to which CCN-like growth factor or SCGF binds, or the biological significance of this protein, there is no immediately obvious patentable use for it. The protein family to which the disclosed protein is said to be a member, contains proteins which have different and divergent biological activities. Additionally, the degree of sequence

homology for the claimed invention to the CCN family is very low (only 27% as disclosed at page 5 of the specification), therefore, it is very uncertain if any biological activity possessed by the claimed protein will be shared with any of the other family members. A search of the art failed to reveal any evidence that would confirm any of the asserted utilities in the instant specification for the claimed protein. One cannot predict which biological activity is possessed by the disclosed protein based on structural similarity alone because of the divergent activities of the members of the family and the relatively low degree of sequence similarity to the other growth factors of the family.

The claimed protein shares some structural similarity to connective tissue growth factor and to the CCN family of proteins based on sequence similarity. The CCN family of proteins includes connective tissue growth factor, CEF-10, CYR-61, FISP-12 and NOV. These proteins share several common structural motifs, including a consensus sequence found in insulin-like growth factor binding proteins, an oligomeric complex forming domain, a binding domain to soluble and matrix molecules, and a dimerization domain. Some of these proteins are thought to be simulators of cell proliferation, but NOV is known to be an inhibitor of cell proliferation (see Snaith et al. Genomics 38: 425-428, 1996). Because the various members of the CCN protein family have different sites of action and different biological effects, it is not clear if the protein of the instant application would be a growth factor, and inhibitor of cell proliferation, a binding protein, or even possibly a transcription factor. In the absence of a knowledge of the receptor to which the claimed protein, SCGF, binds, or the biological significance of this protein,

there is no immediately obvious patentable use for it. To employ a protein of the instant invention in any of the disclosed methods would clearly be using it as the object of further research, which has been determined by the courts to be a utility which, alone, does not support patentability. Since the instant specification does not disclose a credible "real world" use for CCN-like growth factor or SCGF then the claimed invention is incomplete and, therefore, does not meet the requirements of 35 U.S.C. §101 as being useful.

Claims 21-36 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific and substantial credible asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 29 and 31-36 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 29 recites "the mature polypeptide encoded by the human cDNA contained in ATCC Deposit No. 97173", however, the instant specification fails to describe that portion of a protein which is the "mature" portion. Applicant is claiming a very specific species of protein that is not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The structure of "the mature polypeptide" cannot be predicted on the basis of the amino acid sequence of the entire protein since the protein may be proteolytically cleaved *in vivo*, as well as being differentially processed based on which in tissue the protein is expressed. Furthermore, the specification intends mature to encompass forms of the protein which are active, but there is no disclosure of what this activity is or any forms of a protein that have any particular activity (see page 6 of the specification). The claims are directed to a species of protein, the structure of which cannot be determined or predicted from full-length amino acid sequence and the specification does not evidence isolation or conception of the structure of the "the mature polypeptide", therefore, the specification does not provide an adequate written description of a mature protein, and thus the claimed invention, to the extent that it reads upon mature protein, was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 29 and 31-36 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 29 recites "the mature polypeptide encoded by the human cDNA contained in ATCC Deposit No. 97173", however, the recitation of "mature" is indefinite because the metes and bounds of such cannot be determined. The instant specification indicates that the mature protein "comprises 183 amino acids" (see page 4 at [0023] of the instant specification). It is also disclosed at page 6 of the specification that the mature protein is that protein which is remaining after a leader sequence is cleaved by a host cell ([0031]). The specification further states that "[a] mature protein having a prosequence is a proprotein and is an inactive form of the protein. [O]nce the prosequence is cleaved an active mature protein remains" (final sentence of [0031]). Therefore, a mature protein may (1) comprise 183 amino acids, (2) be a protein lacking a leader which is cleaved in a host cell, and/or (3) be an active form of a protein from which a prosequence has been cleaved. In so far as the claims encompass a protein which comprises a particular 183 amino acids as stated at page 4 of the specification, this embodiment is definite. However, in so far as "mature" encompasses forms of the protein which remain after processing in a host cell or those forms which have an activity, these claims are indefinite. One of ordinary skill in the art cannot determine the metes and bounds of what forms are mature and which are not since it is not known

what processing occurs and what activity is possessed by the claimed "mature" protein (see utility rejection above). Because the term "mature" is defined by an unknown activity, the metes and bounds of the claims cannot be determined. Therefore, one could not determine if any particular protein would be considered "mature", and the claims are indefinite for such a recitation.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christine J. Saoud whose telephone number is 571-272-0891. The examiner can normally be reached on Monday-Friday, 6AM-2PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback can be reached on 571-272-0961. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

John LeGuyader
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